PUBLIC HEALTH SERVICE

BIOLOGICAL MATERIALS LICENSE AGREEMENT

This **Agreement** is entered into between the National Institutes of Health ("NIH"), the Centers for Disease Control and Prevention ("CDC"), or the Food and Drug Administration ("FDA"), hereinafter singly or collectively referred to as "**PHS**", agencies of the United States Public Health Service within the Department of Health and Human Services ("**DHHS**") through the Office of Technology Transfer, National Institutes of Health, having an address at 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, USA and _____ ("**Licensee**"), a corporation of _____, having an office at _____.

1. Definitions:

   a. "**Materials**" means the following biological materials including all progeny, subclones, and derivatives thereof:
   _____,
   as described in
   _____
   and developed in the laboratory of
   _____.

   b. "**Licensed Products**" means _____.

   c. "**Net Sales**" means the total gross receipts by **Licensee** for sales of **Licensed Products** or from income from leasing, renting, or otherwise making **Licensed Products** available to others without sale or other dispositions transferring title, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they be with independent sales agencies or regularly employed by **Licensee**, or for the cost of collections.

2. **Licensee** wishes to obtain a license from **PHS** to use the **Materials** provided under this **Agreement** in its commercial research or product development and marketing activities. **Licensee** represents that it has the facilities, personnel, and expertise to use the **Materials** for commercial purposes and agrees to expend reasonable efforts and resources to develop the **Materials** for commercial use and/or commercial research.

3. **PHS** hereby grants to **Licensee** a worldwide, non-exclusive license to make, have made, and use the **Materials** and to make and have made, to use and have used, to sell and have sold, and to offer to sell **Licensed Products** in the **Field(s) of Use** of _____.

4. In consideration of the grant in Paragraph 3 above, **Licensee** hereby agrees to make the following payments to **PHS**:

   a. Within 30 days of its execution of this **Agreement**, a noncreditable, nonrefundable license issue royalty of _____ Dollars ($_____).

b. A nonrefundable minimum annual royalty of _____ Dollars ($_____) which shall be due and payable on January 1 of each calendar year and may be credited against earned royalties for due for sales made in that year. The minimum annual royalty for the first calendar year of this **Agreement** is due and payable within thirty (30) days from the effective date of this **Agreement** and may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1.

c. An earned royalty of _____ percent (___%) of **Net Sales**, which shall be due and payable within sixty days of the end of each calendar year.

All payments required under this **Agreement** shall be paid in US dollars. For conversion of foreign currency to US dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due. All checks and bank drafts shall be drawn on United States banks and shall be payable, as appropriate, to "NIH/Patent Licensing." All such payments shall be sent to the following address: NIH, PO Box 360120, Pittsburgh, PA 15251-6120. Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to US dollars shall be paid entirely by **Licensee**. Interest and penalties may be assessed by **PHS** on any overdue payments in accordance with the Federal Debt Collection Act. The payment of such late charges shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.

5. Upon receipt by **PHS** of the license issue royalty, **PHS** agrees to provide **Licensee** with samples of the **Materials**, excluding progeny, subclones, and derivatives thereof ("**Supplied Materials**"), as available, and to replace such **Supplied Materials**, as available and at reasonable cost, in the event of their unintentional destruction.

6. **Licensee** agrees to make written reports to **PHS** within sixty (60) days after the end of each calendar year. This report shall state the number, description, and aggregate **Net Sales** of **Licensed Products** made, sold, or otherwise disposed of, and the total gross income received by **Licensee** from leasing, renting, or otherwise making **Licensed Products** available to others without sale or other disposition transferring title, during such completed calendar year, and resulting calculation pursuant to Paragraph 4 of payment due. **Licensee** shall submit each such report along with payment due **PHS** for the calendar year covered by the report to **PHS** at the address listed in Paragraph 4 above and shall also send a copy of the report to **PHS** at the Mailing Address for Notices indicated on the Signature Page of this Agreement.

7. **Licensee** agrees to supply the laboratory of Dr. _____ (**PHS**) at no charge reasonable quantities of **Materials** and **Licensed Products** that **Licensee** makes, uses, sells, or offers for sale or otherwise makes available for public use.

8. This **Agreement** shall become effective on the date when the last party to sign has executed this **Agreement** and shall expire _____ ( ) years from this effective date, unless previously terminated under the terms of Paragraphs 16 or 17 below.

9. As part of **Licensee**'s performance under this **Agreement**, **Licensee** agrees to make **Licensed Products** available to the public within _____ months.

10. **Licensee** agrees to retain control over the **Materials**, and not to distribute them to third parties without the prior written consent of **PHS** except as provided in Paragraph 3.

11. **Licensee** agrees that this **Agreement** does not preclude **PHS** from distributing the **Materials** to third parties for research or commercial purposes.

12. By this **Agreement**, **PHS** grants no patent rights expressly or by implication to any anticipated or pending **PHS** patent applications or issued patents.

13. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE **MATERIALS** PROVIDED TO **LICENSEE** UNDER THIS **AGREEMENT**, OR THAT THE **MATERIALS** OR **LICENSED PRODUCTS** MAY BE EXPLOITED WITHOUT INFRINGING THE PATENT RIGHTS OF ANY THIRD PARTIES. **Licensee** accepts license rights to the **Materials** and **Licensed Products** "as is", and **PHS** does not offer any guarantee of any kind.

14. **Licensee** agrees to indemnify and hold harmless the United States Government from any claims, costs, damages, or losses that may arise from or through **Licensee**'s use of the **Materials** or **Licensed Products**. **Licensee** further agrees that it will not by its action bring the United States Government into any lawsuit involving the **Materials** or **Licensed Products**.

15. **Licensee** agrees in its use of any **PHS**-supplied materials to comply with all applicable statutes, regulations, and guidelines, including **PHS** and **DHHS** regulations and guidelines. **Licensee** agrees not to use the **Materials** or the **Licensed Products** for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. **Licensee** agrees not to use the **Materials** or **Licensed Products** for research involving human subjects or clinical trials outside of the United States without notifying **PHS**, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **PHS** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of such research or trials.

16. **Licensee** may terminate this **Agreement** upon sixty (60) days written notice to **PHS**.

17. **PHS** may terminate this **Agreement** if **Licensee** is in default in the performance of any material obligation under this **Agreement**, and if the default has not been remedied within ninety (90) days after the date of written notice by **PHS** of such default.

18. Upon termination or expiration of this **Agreement**, **Licensee** agrees to return all **Materials** and **Licensed Products** to **PHS**, or provide **PHS** with certification of their destruction.

19. Within ninety (90) days of termination or expiration of this **Agreement**, **Licensee** agrees to submit a final report to **PHS**, and to submit to **PHS** payment of any royalties due.

20. **Licensee** is encouraged to publish the results of its research projects using the **Materials** or **Licensed Products**. In all oral presentations or written publications concerning the **Materials** or **Licensed Products**, **Licensee** will acknowledge the contribution of Dr. _____ and the **PHS** agency supplying the **Materials**, unless requested otherwise by **PHS** or Dr. _____.

21. This **Agreement** shall be construed in accordance with US Federal law, as interpreted and applied by the US Federal courts in the District of Columbia. Federal law and regulations will preempt any conflicting or inconsistent provisions in this **Agreement**. **Licensee** agrees to be subject to the jurisdiction of US courts.

22. This **Agreement** constitutes the entire understanding of **PHS** and **Licensee** and supersedes all prior agreements and understandings with respect to the **Materials**.

23. The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

24. Paragraphs 9, 13, 14, and 20 of this **Agreement** shall survive termination or expiration of this **Agreement**.

SIGNATURES BEGIN ON NEXT PAGE

PHS BIOLOGICAL MATERIALS LICENSE AGREEMENT

SIGNATURE PAGE

In Witness Whereof, the parties have executed this **Agreement** on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For **PHS**:

_____ _____

Jack Spiegel, PhD Date
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

Mailing Address for Notices:

Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 USA

For **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of **Licensee** made or referred to in this document are truthful and accurate.):
by:

_____ _____

Signature of Authorized Official Date

_____

Printed Name

_____

Title

Official and Mailing Address for Notices:

_____

_____

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 USC §§3801-3812 (civil liability) and 18 USC §1001 (criminal liability including fine(s) and/or imprisonment).